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PATENT

13581US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Cauci
 Serial No.: 10/698,795
 Filed: 10/31/2003
 For: Enzyme Activities & pH Tests for the Determination of the Risk of Obstetric & Gynecologic Complications in Samples of Body Fluids of Women
 Customer No.: 23719
 PATENT & TRADEMARK OFFICE

Examiner: To be assigned
 Group Art Unit: 1651
 Kalow & Springut LLP
 488 Madison Avenue, 19th Floor
 New York, New York 10022

March 1, 2006

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references set forth on the attached form PTO-1449. Applicants do not admit that the references are "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserves the right to traverse or antedate any such reference. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with Applicants' duty to disclose all information of which they are aware and believe relevant to the examination of the above-identified application, Applicants believe that their invention is patentable.

Certificate of Mailing Under 37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited on the date shown below with the United States Postal Service as first class mail with sufficient postage in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sylvia Goncale
 (Signature)
 Sylvia Goncale
 (Printed Name of Person Signing Certificate)
March 1-2006
 (Date)

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Information Disclosure Statement – Page 2

I. U.S. PATENT DOCUMENTS

<u>Patent No.</u>	<u>Date Issued</u>	<u>Title</u>
5,571,684 to Lawrence <i>et al.</i>	November 5, 1996	Assay for Proline Iminopeptidase and other Hydrolytic Activities

II. U.S. PATENT APPLICATION PUBLICATION

<u>Patent Publication No.</u>	<u>Date Issued</u>	<u>Title</u>
US-2004-0219617-A1	November 4, 2004	Enzymatic test for the determination of the risk of pathologies related to the presence of sialidase or prolidase activity in women body fluid samples

III. FOREIGN PATENT DOCUMENTS

<u>Publication No.</u>	<u>Country</u>	<u>Publication Date</u>
WO 00/24753	European	May 4, 2000
WO 00/55354	European	September 21, 2000
WO 02/065130 A1	WIPO	15 February 2001

III. NON PATENT PUBLICATIONS

McGregor, J.A. et al., "Bacterial Vaginosis is Associated with Prematurity and Vaginal Fluid Mucinase and Sialidase: Results of a Controlled Trial of Topical Clindamycin Cream," American Journal of Obstetrics & Gynecology, Mosby, St. Louis, Mo., Vol. 170, No. 4., April 1994, pages 1048-1060, XP00290115

Briselden, A.M. et al., "Sialidases (Neuraminidases) in Bacterial Vaginosis and Bacterial Vaginosis-Associated Microflora," Journal of Clinical Microbiology, Washington, D.C. US, Vol. 30, No. 3, March 1992-03, pages 663-666, XP002901154

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CAUCI, *et al.* (1998) Impairment of the Mucosal Immune Systems: IgA and IgM Cleavage Detected in Vaginal Washings of a Subgroup of Patients with Bacterial Vaginosis, *Journal of Infectious Diseases*, 178:1698-1706.

CAUCI, *et al.* (1998). Immunoglobulin A response against *Gardnerella vaginalis* hemolysin and sialidase activity in bacterial vaginosis, *American Journal of Obstetrics and Gynecology*, 178:511-515.

CAUCI *et al.* (1996) Specific immune response against *Gardnerella vaginalis* hemolysin in patients with bacterial vaginosis, *American Journal of Obstetrics and Gynecology*, 175/6:1601-1605. (Abstract Only)

CAUCI *et al.* (2003) Determination of immunoglobulin A against *Gardnerella vaginalis* hemolysin, sialidase, and prolidase activities in vaginal fluid: implications for adverse pregnancy outcomes, *Journal of Clinical Microbiology*, 41/1:435-438.

European Search Report for EP 04 02 2918 (2 pages)

International Search Report for PCT/IT01/00069 (3 pages)

International Search Report for PCT/IT01/00068 (2 pages)

Because no action has been taken on the merits, Applicants submit that no fee is due at this time. However, if a fee is deemed necessary, please charge Deposit Account No. 11-0171.

Respectfully submitted,



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<p style="text-align: center;">O I P E INFORMATION DISCLOSURE CITATION <small>(Use several sheets if necessary)</small></p> <p style="text-align: right;">MAR 07 2006</p> <p style="text-align: center;">U.S. PATENT DOCUMENTS</p>				Docket Number (Optional) 13581US	Application Number 10/698,795			
				Applicant(s) CAUCI				
				Filing Date October 31, 2003	Group Art Unit 1651			
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		5,571,684	11-05-96	Lawrence et al				
U.S. PATENT APPLICATION PUBLICATIONS								
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
		US-2004-0219617-A1	11-04-04	CAUCI				
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
		WO 00/24753	05-04-00	WO			✓	
		WO 00/55354	09-21-00	WO				✓
		WO 02/065130 A1	09-15-00	WO				✓
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
		McGregor, J.A. et al., "Bacterial Vaginosis is Associated with Prematurity and Vaginal Fluid Mucinase and Sialidase: Results of a Controlled Trial of Topical Clindamycin Cream." American Journal of Obstetrics & Gynecology, Mosby, St. Louis, Mo., Vol. 170, No. 4., April 1994, pages 1048-1060, XP00290115						
		Briselden, A.M. et al., "Sialidases (Neuraminidases) in Bacterial Vaginosis and Bacterial Vaginosis-Associated Microflora," Journal of Clinical Microbiology, Washington, D.C. US, Vol. 30, No. 3, March 1992-03, pages 663-666, XP002901154						
EXAMINER				DATE CONSIDERED				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								



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Applicant(s)

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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

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